

### **REMARKS**

Claims 1-26 are currently pending. In the Final Office Action mailed December 30, 2008 ("Final Office Action") claims 1-26 were rejected. Applicants respectfully request reconsideration and allowance of the claims in light of these remarks.

#### **Specification**

The specification is amended to correct the claim for priority under 37 CFR 1.78(a)(5). This application claimed priority to U.S. Patent Application Serial No. 09/722,070, now US Patent 7,470,236 ('236). The '236 patent properly claimed the benefit of priority to US Provisional Application Serial No. 60/167,416 ('416), filed November 24, 1999 and thus the present application is also entitled to priority from the '416 provisional. At the time of filing, however, the present application inadvertently made a claim for priority directly to the '416 provisional, rather than indicating that the priority to the provisional was achieved through the parent application. As amended herein, the present application now claims priority through the parent application. Furthermore, because the claim for priority to the '416 provisional was recognized by the Patent Office, as evidenced by the inclusion of the '416 provisional under the "Domestic Priority" section of the filing receipt mailed July 6, 2004, no petition or fee is believed necessary for this correction. (See MPEP § 201.11(V)).

#### **Claim Rejections - 35 USC 103(a)**

##### **Claims 1-26**

Independent claim 1 was rejected under 35 USC 103(a) as being unpatentable over US Patent 5,474,558 to Neubardt ("Neubardt") in view of Calancie et al's article entitled "Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation" ("Calancie") in view of US Patent 5,806,522 to Katims ("Katims"). The Applicants respectfully traverse this rejection as follows.

The Applicants respectfully submit that even if there was a reason that would have prompted a person of skill in the art to modify the Neubardt reference as proposed (an issue that is not conceded herein), the proposed combination of Neubardt, Calancie, and Katims would nevertheless fail to disclose all the elements of claim 1. More specifically, the references (both alone and in combination) fail to disclose a method of determining structural integrity of a pedicle that includes "automatically increasing said electrical stimulus **until said onset neuro-**

**muscular response is detected**, wherein the automatic increasing is controlled by said neurophysiology system.”

The failure of Neubardt and Calancie to disclose a method including the step of “automatically increasing said electrical stimulus until said onset neuro-muscular response is detected, wherein the automatic increasing is controlled by said neurophysiology system,” is acknowledged beginning on page 4 of the Office Action. Applicants respectfully submit that Katims does not fill this void in the teachings of Neubardt and Calancie.

Katims teaches an automated device and method for determining “*perception thresholds*,” which relate to the sensory pathways of the neurological system. In the current perception threshold tests taught by Katims, the current level at which a patient feels or perceives the application of a stimulation signal (or, feels pain from the signal) is determined. While Katims does teach methods in which the intensity of an electrical stimulus is automatically increased in order to determine the perception threshold, the automatic increase does not continue “until said *onset neuro-muscular response is detected*,” as is required in claim 1. Instead, the increase in the electrical stimulus is continued until the patient perceives the stimulation being applied (as he may indicate, for example, by depressing a button when he thinks he feels the stimulus). As noted in the Office Action, Katims suggests that “physiological measures may be ascertained using the present invention . . . in conjunction with physiological monitoring to measure physiological responses to the electrical stimulation.” However, as is consistent with the remainder of Katims, the physiologic measures would be used for “assessing sensory function in patients,” (*Col. 34, ln. 13*) and would thus again not include automatically increasing an electrical stimulus until an onset neuro-muscular response is detected.

Indeed, as might be expected for a device and method used to detect perception or sensory thresholds, Katims is completely silent with regard to the detection of a neuro-muscular response period, and thus necessarily fails to teach “automatically increasing said electrical stimulus **until said onset neuro-muscular response is detected**, wherein the automatic increasing is controlled by said neurophysiology system.”

Applicants respectfully submit that independent claim 1 is patentable over Neubardt, Calancie, Katims, and all other references cited in the record. Claim 1 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested. Claims 2-26, being dependent upon and further limiting independent claim 1, should be allowable for the

reasons set forth in support of the allowability of claim 1, as well as the additional inventive features they describe.

## Conclusion

Applicants respectfully request reconsideration and allowance of claims 1-26. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

The Applicant hereby authorizes a payment of the \$555.00 fee for the 3 month Extension of Time and the \$405.00 fee for filing an RCE to be charged to Deposit Account No.: 50-2040 for Customer No.: 30,328. No other fees are believed due at this time, however, in the event additional fees are necessary, please apply any charges or credits to Deposit Account No.: 50-2040 for Customer No.: 30,328.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,  
NUVASIVE, INC.

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